UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,391	08/21/2003	Martin Gleave	UBC.P-035	9734

57381 7590 09/18/2006

Marina Larson & Associates, LLC
P.O. BOX 4928
DILLON, CO 80435

EXAMINER
BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/646,391	GLEAVE ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 14* is/are rejected.

7)☒ Claim(s) *2-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 7/12/2006. Rejections and/or objections not reiterated from the previous office action mailed 4/14/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11 and 12 have been withdrawn from consideration, as well as the subject matter that is not drawn to antisense oligonucleotides that span the translation initiation site or specifically to SEQ ID NO: 4.

With entry of the amendment filed on 7/12/2006, claims 1-12 and 14 are pending in the application.

This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments--Claim Objections

Claims 3, 6 and 9 stand objected to for the reasons of record in the office action mailed 4/8/05 and maintained in the office actions mailed 9/7/05 and 4/14/2006.

Applicant asserts that the restriction should be treated as a species election. As explained in the previous office actions, each of the sequences are considered to be

unrelated, since each sequence is structurally and functionally independent and do not share a common core. As such the Markush/genus of sequences that are instantly claimed are not considered to constitute proper genus, and therefore are subject to restriction.

As explained in the office actions mailed 9/7/05 and 4/14/2006, the subject matter of claims 3, 6 and 9 that is not drawn to instant SEQ ID NO: 4 and the translation initiation site, is considered withdrawn as being drawn to non-elected subject matter and the claims are objected to because they contain subject matter that is withdrawn. Therefore, claim 3 is objected to for containing subject matter that is not drawn to the translation initiation site. The sequences of claims 6 and 9 were restricted because the sequences are not considered proper Markush members.

Furthermore, if applicant amends claim 6 to cancel the withdrawn subject matter of claim 6, claims 6 and 7 will be substantial duplicates. If applicant amends claim 9 to cancel the withdrawn subject matter of claim 9, claims 9 and 10 will be substantial duplicates as well.

Response to Arguments--Claim Rejections - 35 USC § 112

Claims 1 stands rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the office action mailed 4/14/2006.

Applicant asserts that the examiner has not presented reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims. Contrary to applicant's assertion, the examiner has not only

argued that a person skilled in the art could not envisage the scope of the instantly recited therapeutic agents, but has also explained why one of ordinary skill in the art would not recognize that applicant was in possession of the instantly recited invention at the time the invention was made.

As explained in the office action mailed on 4/14/2006, the instant claim encompasses a method for treatment of melanoma in a mammalian subject comprising the step of administering any therapeutic agent effective to reduce the amount of clusterin in the melanoma cells. Given the breadth of therapeutic agents embraced by the claim that have not been described in the instant specification and have not yet even been described in the art, one of ordinary skill in the art would not recognize that applicant was in possession of such a large scope of therapeutic agents. For example, the claim encompasses administering agents such as small molecule inhibitors, antibodies, siRNAs, miRNAs, ribozymes, antisense oligonucleotides, and aptamers, as well as embraces the administration of any other therapeutic agent that reduces the effective amount of clusterin in melanoma cells that are yet to be discovered.

As explained in the office action mailed on 4/14/2006, the method utilizing one specific antisense oligo, SEQ ID NO: 4, in an antisense treatment method for various cancers, as exemplified in the 1.132 declaration, does not adequately describe the scope of the instantly recited genus which encompasses administering not only any antisense oligonucleotide, but any therapeutic agent to reduce the effective amount of clusterin in melanoma cells.

Applicant asserts that method claims routinely contain limitations such as "measuring the amount of X" without disclosing every possible way of making the measurement. Applicant's analogy between a method of measuring the amount of X and the instant method of treating melanoma is not considered persuasive. A method of treating is considered substantially more unpredictable than a measuring process and therefore the genus is more unpredictable. Furthermore, the examiner is not asserting that applicant must disclose every possible way of accomplishing their method, but rather is asserting that applicant must describe a sufficient number of species to describe the instantly recited genus. In the instant case, description of an antisense oligonucleotide or siRNA therapeutic with reduction to practice of one antisense oligonucleotide is not considered to describe the genus of administering any therapeutic agent to reduce the amount of clusterin in melanoma cells to treat melanoma in a mammalian subject.

Applicant's instant invention is a method for treatment of melanoma in a mammalian subject comprising the step of administering a therapeutic agent effective to reduce the amount of clusterin in the melanoma cells. Contrary to applicant's argument regarding In re Fuetterer, the examiner is not requiring for applicant to discover which of the possible therapeutic agents will function properly in the method. The examiner is requiring a description of an adequate number of species of therapeutic agents to be used by the method so that one of ordinary skill in the art would recognize that applicant was in possession of the instantly recited method at the time the invention was made. It

is not apparent that applicant was in possession of a method of treating melanoma with any therapeutic agent effective to reduce clusterin based on the disclosure.

There is no requirement for applicant to describe every possible therapeutic agent that is embraced by the instant claim, but there is a requirement for applicant to provide a written description of the invention commensurate in scope with the claims. In the instant case, applicant has not provided a description of the invention commensurate with the scope of the instant claim, as explained above.

New Objections/Rejections

Claim Objections

The claims are objected to because the lines are crowded too closely together, making reading difficult. Substitute claims with lines one and one-half or double spaced on good quality paper are required. See 37 CFR 1.52(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The invention of the above claim is drawn to a method for treatment of melanoma in a mammalian subject, comprising the step of administering to the subject a therapeutic agent effective to reduce the effective amount of clusterin in the melanoma cells, wherein the therapeutic agent is an oligonucleotide.

At the outset, it is noted that the claimed method does not recite a specific type of oligonucleotide agent, but rather refers to the administration of any oligonucleotide agent effective to reduce the effective amount of clusterin in the melanoma cells.

The claim encompasses a method of administering any oligonucleotide therapeutic agent effective to reduce the effective amount of clusterin in melanoma cells, including antisense oligonucleotides, siRNAs, miRNAs, ribozymes, and aptamers, as well as embraces the administration of any other oligonucleotide therapeutic agent that reduces the effective amount of clusterin in melanoma cells that are yet to be discovered.

Although the specification discloses antisense and RNAi as means of reducing the amount of clusterin in melanoma cells, the specification does not describe any other oligonucleotide therapeutic agent that is effective to reduce the effective amount of clusterin in melanoma cells in a mammalian subject to describe the instantly claimed genus of administering any therapeutic agent that is effective to reduce the effective amount of clusterin in melanoma cells in a mammalian subject. The method utilizing one specific antisense oligo, SEQ ID NO: 4, in an antisense treatment method for

various cancers, as exemplified in the 1.132 declaration, does not adequately describe the scope of the instantly recited genus which encompasses administering not only any antisense oligonucleotide, but any therapeutic agent to reduce the effective amount of clusterin in melanoma cells.

One of ordinary skill in the art could not make and administer such therapeutic agents to reduce the effective amount of clusterin in melanoma cells without knowledge of the specific types of agents. Given the breadth of therapeutic agents embraced in the instantly claimed genus, one could not envision the member genus of agents.

The scope of the claimed invention is broad and the skilled artisan would not be able to envisage the genus claimed of therapeutic agents effective to reduce the effective amount of clusterin in melanoma cells such that the skilled artisan would recognize that the applicant was in possession of the claimed genus at the time of filing.

Allowable Subject Matter

Claims 2, 4, 5, 7, 8, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and if each of the objections/rejections of the base claim and any intervening claims are overcome.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER